K033436

MAR 16 2005

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# SECTION B: 510(k) SUMMARY

**Submitter:**
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

**Contact:**
Moira Barton
Regulatory Affairs Manager
(480) 763-5350 (o)
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mbarton@alliance-medical.com

**Date of preparation:** October 3, 2003

**Name of device:**
*Trade/Proprietary Name:* Reprocessed Ultrasound Catheter
*Common or Usual Name:* Diagnostic Ultrasound Transducer Catheter
Classification Name: *Catheter, Intravascular, Diagnostic*

**Predicate device:**

**K992631** AcuNav™ Diagnostic Ultrasound Catheter

**Device description:** Diagnostic ultrasound catheters are specially designed ultrasonic catheters that provide two-dimensional imaging using an ultrasound transducer. The ultrasound transducer is at the distal tip of the catheter and can be positioned for ultrasound imaging by a steering mechanism that rotates the catheter tip and variable deflection. Diagnostic ultrasound catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer. The ultrasound catheter is 10 French with 90 cm insertion length.

**Intended use:** Reprocessed Diagnostic Ultrasound Catheters are intended for intravascular or intracardiac ultrasound imaging in order to provide visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart. The device is intended for use in the right heart only.

**Indications statement:** Reprocessed Diagnostic Ultrasound Catheters are indicated for visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. The Reprocessed Diagnostic Ultrasound Catheter is intended for use in the right side of the heart only.

**Technological characteristics:** The design, materials, and intended use of Reprocessed Ultrasound Catheters are identical to the predicate devices. The

mechanism of action of Reprocessed Ultrasound Catheters is identical to the predicate devices in that the same standard mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Alliance Medical Corporation's reprocessing of ultrasound catheters includes removal of adherent visible soil and decontamination. Each individual ultrasound catheter is tested for appropriate function of its components prior to packaging and labeling operations.

**Performance data:** Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Ultrasound Catheters.

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Ultrasound Catheters perform as originally intended.

**Conclusion:** Alliance Medical Corporation concludes that the modified device (the Reprocessed Ultrasound Catheter) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Alliance Medical Corporation
c/o Ms. Moira Barton
Regulatory Affairs Manager
10232 South 51st Street
Phoenix, Arizona 85044

Re: K033436
Trade/Device Name: Reprocessed Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (Two)
Product Code: NLI
Dated: January 19, 2004
Received: January 21, 2005

Dear Ms. Barton:

This letter corrects our substantially equivalent letter of March 16, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

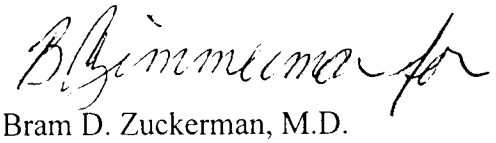
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Divison of Cardioascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure (2)

| Original model found to be SE |
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| AccuNav™ Diagnostic Ultrasound Catheter, Model 08255790 |

# 2. Indications for Use Statement

**510(k) Number (if known):** K033436

**Device Name:** Alliance Medical Corporation Reprocessed Ultrasound Catheter

**Indications for Use:** Reprocessed Diagnostic Ultrasound Catheters are indicated for visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart, as well as measurement of blood flow. The Reprocessed Diagnostic Ultrasound Catheter is intended for use in the right side of the heart only.

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033436